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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,897	10/25/2001	Manfred Eigen	EIGEN ET AL (DIV)	8308

7590 08/27/2003

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1077 Northern Boulevard
Roslyn, NY 11576

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

13

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,897

Applicant(s)

Eigen et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 6, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-72 is/are pending in the application.
- 4a) Of the above, claim(s) 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-68 and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment filed 6/6/2003 has been entered. Following the entry of the amendment, claims 47-72 are pending and claim 69 is withdrawn as non-elected group.

Rejections and/or objected from the previous office action are hereby withdrawn. The following rejections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 47-68 and 70-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5 and 13 of U.S. Patent No. 6,423,516. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 47-72 are drawn to a process for destabilizing a viral

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quasi-species-distributing without inducing resistance to therapeutics agents, while claims 1, 3-5 and 13 of U.S. Patent No. 6,423,516 are drawn to a method of destabilizing viral quasi-species comprising treating a target cell with a replicator nucleic acid. The method of claims 1, 3-5 and 13 of U.S. Patent No. 6,423,516 is a genus that would render obvious over the species method claims 47-72 of the instant application. Thus, it is obviousness-type double patenting rejection.

Claim Objections

3. Claims 65 and 68 are objected to because of the following informalities: the word “eucaryotic” in claim 65 and the word “metagenesis” in claim 68 might be a typographic error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 50-54, 56-57, 60-62, 66 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 50-51 and 53 are vague and indefinite because the phrase “selecting” in claims 50-51 and 53 has no antecedent basis. It is suggested to add the phrase “further comprising” before the phrase “selecting”.

b. Claims 52 is vague and indefinite because the phrase “via the infiltration of a viral replication system into the virus population with subsequent infection of target cells of the virus infection ...” has no antecedent basis since in claim 47 there is no mention about the infiltration of a viral replication system. Clarification is required.

c. Claim 54 is vague and indefinite because the phrase “the virus population” has no antecedent basis from where it is referred. In addition it is unclear regarding the phrase “a manner according to gene therapy” Since in the specification, there is no definition regarding what is the manner according to the gene therapy. Furthermore, the gene therapy is only applied to human and not to any target cells. Clarification is required.

d. Claim 56 is vague and indefinite because the language is unclear in the claim. It can be determined what is the definition of “genetechnical procedure” or whether it is gene therapy. Clarification is required.

e. Claim 57 is vague and indefinite because the phrases “ in the transformed virus individual or in the transformed target cell” has no antecedent basis since in claim 47 there is no transformation occurred.

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f. Claim 60 is vague and indefinite because of the phrase “a combination of the replication system”. It is unclear what replication system is referred since there is a defective replication system in quasispecies and the replication system in the wild type virus.

g. Claims 61, and 72 are vague and indefinite because the preamble is for the treatment or prophylaxis of viral diseases, but there is no human being which is treated to accomplish the process. Clarification is required.

h. Claim 62 is vague and indefinite because the phrase “host cells are the target cells of the viral infection ...” has no antecedent basis since in claim 47, there is no host cells and target cells of the viral infection.

I. Claim 66 is vague and indefinite because of the phrase “they”. It is unclear what is encompassed in the phrase from claim 63.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 63-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikeda et al. (EP 0215 987).

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Ikeda et al. disclose a reverse transcriptase encoded by cauliflower mosaic virus, a cloned gene encoding for polypeptide having the reverse transcriptase and yeast used as an eukaryotic host (See the Abstract and pg. 11, column 19, lines 13-31).

The teachings of Ikeda et al. anticipate the limitations of claims 63-66 that an agent comprises a nucleic acid coding for a nucleic acid and a viral replication system and transformed viruses or eukaryotic cells or procaryotic cells.

Summary

8. No claims allowable.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

^{J.T.}
August 15, 2003


ETHAN WHISENANT
PRIMARY EXAMINER